

K103338

pg 1 of 3

NOV - 1 2011

**Premarket Notification  
510(k) Summary  
(As Required by 21 CFR 807.93)**

This 510(k) Summary of safety and effectiveness for the New Star Model CoolTouch VariaBreeze Nd:YAG Surgical Laser system is submitted in accordance with the requirements of the SMDA 1990 and following guidance concerning the organization and content of a 510(k) summary.

**Submitter:** New Star Lasers, Inc. d.b.a. CoolTouch Inc.

**Address:** 9085 Foothills Boulevard  
Roseville, CA 95747

**Contact Person:** Natalie Vollrath  
Quality and Regulatory Manager

**Telephone/Fax/Email:** (916) 677-1912 – Phone  
(916) 677-1901 – Fax  
nvollrath@newstarlasers.com - Email

**Date prepared:** September 30, 2011

**Device Trade Name:** CoolTouch VariaBreeze™ Nd:YAG Surgical Laser

**Common Name:** Nd: YAG Surgical Laser

**Classification Name:** Instrument, surgical, powered, laser  
79-GEX  
21 CFR §878.4810

**Legally Marketed Predicate Devices:**

- CoolTouch Varia Nd:YAG laser system (K092964)
- PinPointe USA, Inc. PinPointe FootLaser Nd:YAG laser system (K093457)

**Device Description:** The CoolTouch VariaBreeze Laser System is an Nd:YAG laser using a flashlamp-pumped solid state laser rod to produce laser emission at 1064 nm. The laser consists of a cabinet that houses the following:

- Control panel with microcontroller and emergency stop button, standby button, ready button, and key switch
- Connector port for fiber optic delivery system
- Remote interlock connector
- 630 to 680 nm diode aiming beam
- Power supply
- Cooling system
- Connector port for footswitch and power cord

K 103338

Pg 2 of 3

Delivery devices for the VariaBreeze include:

- CoolBreeze Handpiece for CoolBreeze Mode—Contains non-replaceable fiber optic within a flexible cable connected to the laser. A standoff at the tip allows for non-contact use, and a control dial is used to set the spot size from 2mm to 10mm. The handpiece also has cryogen for topical cooling. The handpiece is cleanable and reusable.
- Toenail Handpiece for Toenail Mode—The fiber optic cable attaches to the laser. The handpiece features a standoff at the tip to provide the correct placement for laser delivery to the treatment site and is reusable and cleanable.

Intended Use:

The CoolTouch VariaBreeze with CoolBreeze® Handpiece is intended for:

Podiatry: Ablation, vaporization, incision, excision, and coagulation of soft tissue including matrixectomy, periungal and subungal warts, plantar warts, radical nail excision, and neuromas.

The CoolTouch VariaBreeze with Toenail Handpiece is intended for:

For use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes *Trichophyton rubrum* and *T. mentagrophytes*, and/or yeasts *Candida albicans*, etc.).

Comparison:

The Cooltouch VariaBreeze has the same principle of operation, the same wavelength and essentially the same pulse energy rate as the predicate devices.

Nonclinical Performance Data

None

Clinical Performance Data:

None

K103338 pg 3 of 3

Technological Characteristics:

| Characteristic        | CoolTouch<br>Varia<br>Laser System<br>K092964  | CoolTouch<br>VariaBreeze<br>Laser System<br>K103338 |
|-----------------------|--|---|
| Laser Medium          | Nd:YAG   | Nd:YAG  |
| Wavelength            | 1064 nm  | 1064 nm   |
| Aiming Beam           | 532 nm   | 532 nm  |
| Output Power<br>(max) | 36W max  | 30W   |
| Energy per Pulse      | Variable to 3.9 Joules                         | 20-200 mJ, 500-1000 mJ                              |
| Pulse Duration        | 600 $\mu$ sec                                  | 100-700 $\mu$ sec                                   |
| Exposure              | Single pulse or repeat for<br>continuous burst | Continuous  |
| Repetition Rate       | 6-200 Hz                                       | 5-100 Hz  |
| Spot Size             | 2 – 10 mm                                      | 2 – 10 mm   |
| Dimensions            | 31"H x 18"W x 21"D                             | 31"H x 18"W x 21"D                                  |
| Weight                | 160 lbs (73kg) console                         | 160 lbs (73 kg) console                             |
| Power<br>Requirements | 115VAC, 230VAC<br>50/60Hz                      | 115VAC, 230VAC<br>50/60Hz                           |

| Characteristic        | Patholase<br>PinPointe<br>FootLaser<br>Laser Systems<br>K093547 |                           |                           | CoolTouch<br>VariaBreeze<br>Laser System<br>K103338 |
|-----------------------|---|---------------------------|---------------------------|---|
| Laser Medium          | Nd:YAG  |                           |                           | Nd:YAG  |
| Wavelength            | 1064 nm   |                           |                           | 1064 nm   |
| Aiming Beam           | 630-680 nm  |                           |                           | 532 nm  |
| Output Power<br>(max) | 6W  | 30W                       | 100W                      | 30W   |
| Energy per Pulse      | 20-<br>200<br>mJ  | 20-1000<br>mJ             | 20-3500<br>mJ             | 20-200 mJ, 500-1000 mJ                              |
| Pulse Duration        | 100-<br>700<br>$\mu$ sec  | 350-<br>3000<br>$\mu$ sec | 350-<br>3000<br>$\mu$ sec | 100-700 $\mu$ sec                                   |
| Exposure              | Continuous  |                           |                           | Continuous  |
| Repetition Rate       | 5-100 Hz  |                           |                           | 5-100 Hz  |
| Spot Size             | 1 mm (published)  |                           |                           | 1 mm  |
| Dimensions            | 14"H x 7"W x 16"D   |                           |                           | 31"H x 18"W x 21"D                                  |
| Weight                | 36 lbs (16kg) console   |                           |                           | 160 lbs (73 kg) console                             |
| Power<br>Requirements | 90-130VAC,<br>200-240 VAC<br>50/60 Hz                           |                           |                           | 115VAC, 230VAC<br>50/60Hz                           |

Conclusion:

The CoolTouch VariaBreeze Nd:YAG Laser System is substantially equivalent to the predicate devices for the indications requested.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

May 13, 2013

New Star Lasers, Inc.  
% Ms. Natalie Vollrath  
Quality and Regulatory Manager  
9085 Foothills Boulevard  
Roseville, California 95747

Re: K103338

Trade/Device Name: CoolTouch VariaBreeze Nd:YAG Laser System  
Regulation Number: 21 CFR 878.4810  
Regulation Name: Laser surgical instrument for use in general and  
plastic surgery and in dermatology  
Regulatory Class: Class II  
Product Code: PDZ, GEX  
Dated: October 25, 2011  
Received: October 25, 2011

Dear Mr. Vollrath:

This letter corrects our substantially equivalent letter of November 01, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours, FOR

**Peter D. Rumm -S**

Mark N. Melkerson  
Acting Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K103338

pg 1 of 1

**Indications For Use Statement**

**510(k) Number:**

**Device Name:** CoolTouch VariaBreeze Nd:YAG Laser System

**Indications for Use:**

**For CoolTouch VariaBreeze™ with CoolBreeze® Handpiece:**

Podiatry: Ablation, vaporization, incision, excision, and coagulation of soft tissue including matrixectomy, periungual and subungual warts, plantar warts, radical nail excision, and neuromas.

**For CoolTouch VariaBreeze™ with Toenail Handpiece:**

Indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes *Trichophyton rubrum* and *T. mentagrophytes*, and/or yeasts *Candida albicans*, etc.).

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter Use         
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE) Nil R. [Signature] for [Signature]  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K103338

Page 1 of 1